

(b) After a hearing commences, the presiding officer may issue a summary decision on any issue in the hearing if the presiding officer determines from the material submitted in connection with the hearing, or from matters officially noticed, that there is no genuine and substantial issue of fact respecting that issue. For the purpose of this paragraph, a hearing commences upon the receipt by FDA of a request for hearing submitted under § 16.22(b).

(c) The Commissioner or his or her delegate may review any summary decision of the presiding officer issued under paragraph (b) of this section at the request of a party or on the Commissioner's or his or her delegate's own initiative.

[53 FR 4615, Feb. 17, 1988]

Subpart C—Commissioner and Presiding Officer

§ 16.40 Commissioner.

Whenever the Commissioner has delegated authority under part 5 on a matter for which a regulatory hearing is available under this part, the functions of the Commissioner under this part may be performed by any of the officials to whom the authority has been delegated, e.g., a center director.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

§ 16.42 Presiding officer.

(a) An FDA employee to whom the Commissioner delegates such authority, or any other agency employee designated by an employee to whom such authority is delegated, may serve as the presiding officer and conduct a regulatory hearing under this part.

(b) In a regulatory hearing required by the act or a regulation, the presiding officer is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Commissioner, who has participated in such investigation or action.

(c)(1) The Commissioner or the delegate under § 16.40 is not precluded by this section from prior participation in the investigation or action that is the subject of the hearing. If there has

been prior participation, the Commissioner or the delegate should, if feasible, designate a presiding officer for the hearing who is not a subordinate. Thus, if the Commissioner's authority to make a final decision has been delegated to a center director, the presiding officer may be an official in another center or the office of the Commissioner. The exercise of general supervisory responsibility, or the designation of the presiding officer, does not constitute prior participation in the investigation or action that is the subject of the hearing so as to preclude the Commissioner or delegate from designating a subordinate as the presiding officer.

(2) The party requesting a hearing may make a written request to have the Commissioner or the delegate under § 16.40 be the presiding officer, notwithstanding paragraph (c)(1) of this section. If accepted, as a matter of discretion, by the Commissioner or the delegate, the request is binding upon the party making the request.

(3) A different presiding officer may be substituted for the one originally designated under § 16.22 without notice to the parties.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

§ 16.44 Communication to presiding officer and Commissioner.

(a) Regulatory hearings are not subject to the separation of functions rules in § 10.55.

(b) Those persons who are directly involved in the investigation or presentation of the position of FDA or any party at a regulatory hearing that is required by the act or a regulation should avoid any off-the-record communication on the matter to the presiding officer or the Commissioner or their advisors if the communication is inconsistent with the requirement of § 16.95(b)(1) that the administrative record be the exclusive record for decision. If any communication of this type occurs, it is to be reduced to writing and made part of the record, and the other party provided an opportunity to respond.

(c) A copy of any letter or memorandum of meeting between a participant in the hearing and the presiding